Impact of anti-tumor necrosis factor antibodies treatment on the semen quality of inflammatory bowel diseases patients

Published: 27-05-2009
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To study the influence of anti-TNF therapy on the semen quality of IBD patients

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sexual function and fertility disorders
Study type	Observational invasive

Summary

ID

NL-OMON33788

Source
ToetsingOnline

Brief title
AntiTNF and semen quality in IBD patients

Condition

- Sexual function and fertility disorders

Synonym
fertility, reproduction

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anti-tumor necrosis factor antibody, fertility, inflammatory bowel diseases, males

Outcome measures

Primary outcome

- changes from the baseline (prior the treatment) semen quality and quantity in

the 3rd and 6th month of the antiTNF treatment

Secondary outcome

not applicable

Study description

Background summary

Inflammatory bowel diseases (IBD) affect patients in the reproduction age. Therefore, the frequently encountered clinical problem concerns the impact of the disease and therapy on the IBD patients` fertility. Anti-tumor necrosis factor antibodies (antiTNF) represent a recently introduced therapeutics effective in IBD. Due to the increasing use of antiTNF in the young IBD patients` population with conception wish, it is important to study the impact of these agents on the fertility of IBD patients.

Study objective

To study the influence of anti-TNF therapy on the semen quality of IBD patients

Study design

Observational study without invasive interventions

Study burden and risks

The treatment decision will be guided by standard health care considerations. The extra burden resulting from the participation in this study will include:
- donation of the sperm for semen analysis prior the treatment with antiTNF, in the 3rd and 6th month of the treatment and give blood for hormonal analysis.
- filling out the disease activity questionnaire at the inclusion and

subsequently every three months during the follow-up
- outpatient clinic visits every three months, in total 3 times
- venepuncture at every outpatient visit

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- male IBD patients with an absolute indication and no contra-indication for anti-TNF medication
- age between 18 and 50 years
- informed consent

Exclusion criteria

- severe disease activity - Crohn`s Disease Activity Index >300
- incapacity to understand the informed consent
- previously documented sub/infertility

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2009
Enrollment:	20
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Humira
Generic name:	adalimumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Remicade
Generic name:	infliximab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	27-05-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-10-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2008-005619-16-NL
CCMO	NL24890.078.09